NexImmune Reports First Quarter 2022 Financial Results and Provides Business Updates

May 12, 2022

- *Clinical data updates for the Company's two lead product candidates in Phase 1/2 clinical trials expected in 2H2022*
- *Investigational New Drug (IND) submission for NEXI-003, the Company's first product for solid tumors, planned for 1H2022*
- *Plans to report additional preclinical and IND enabling data for the AIM Injectable platform in 2H2022*

GAITHERSBURG, Md., May 12, 2022 (GLOBE NEWSWIRE) -- NexImmune, Inc. (Nasdaq: NEXI), a clinical-stage biotechnology company developing a novel approach to immunotherapy designed to orchestrate a targeted immune response by directing the function of antigen-specific T cells, today reported financial results for the first quarter of 2022.

"This quarter, we have continued to execute on our clinical and corporate strategy, taking the necessary steps to achieve our upcoming catalysts for the remainder of this year," said Kristi Jones, Chief Executive Officer. "We remain on track to provide a clinical update for the NEXI-001 trial in AML during the second half of 2022, and to provide an update on the expansion cohort in the NEXI-002 trial in relapsed / refractory multiple myeloma. We also plan to file our first solid tumor IND application for HPV-associated malignancies in the near term. In parallel, we are advancing IND-enabling work for our AIM injectable modality and expect to provide updates on preclinical data for oncology and autoimmune indications throughout the second half of the year. With our new target discovery collaborations, we are well-positioned to leverage our modular AIM platform for efficient and rapid new product development. Overall, I am excited with our progress and focus on execution to deliver on upcoming catalysts."

First Quarter 2022 Clinical and Business Highlights

Clinical and Preclinical Updates

NEXI-001

- Robust immune responses with signs of clinical activity across all dose levels to date
- NEXI-001 continues to be well tolerated across all dose levels administered to date, with no Grade ≥3 treatment-related adverse events, including infusion reactions, GVHD, CRS or neurotoxicity (ICANS), reported
- Due to the favorable emerging clinical profile, plans are underway to expand the addressable population with an additional study arm to include patients with haplo-identical donors
- Enrollment continues, and updated clinical results are expected to be announced in the second half of 2022

NEXI-002

- Expansion phase is ongoing
- In this heavily pre-treated population, evidence of immune response and signals clinical activity have been observed. NEXI-002 continues to be well tolerated with no Grade ≥3 treatment-related adverse events, including infusion reactions, GVHD, CRS or neurotoxicity (ICANS), reported
- Manufacturing achieved higher final cell count yield in recent products by adjusting prior treatment washout period, updating cell collection guidance and other process adjustments
- Further clinical data from the Phase 1/2 trial are expected in the second half of 2022

NEXI-003

- Preclinical data supporting the selection of multiple immunogenic antigen peptides commonly expressed on HPV-associated tumors and a cancer survival antigen was presented during the Society for Immunotherapy of Cancer's Annual Meeting (SITC 2021) in November 2021
- Finalized antigen selection for NEXI-003 and manufactured nanoparticles for clinical trials
- Investigational New Drug (IND) submission planned for the first half of 2022

Injectable AIM nanoparticle programs and other preclinical research

- Advanced *in vivo* and preclinical work to support the development of AIM injectable nanoparticles as a therapeutic in oncology and autoimmune diseases
- Advanced work with Yale University Professor Kevan Herold to evaluate AIM INJ nanoparticles for type 1 diabetes. A JDRF grant award will support the collaboration
- Announced a strategic partnership with Zephyr AI in oncology for novel target discovery and validation to support target selection for potential future products candidates
- Announced research collaboration with Rutgers, The State University of New Jersey, for neuroendocrine tumor checkpoint

targets, which may have utility in other cancers
- Announced research collaboration with NYU Langone Perlmutter Cancer Center for melanoma neo-antigen-specific CD8+ T cell expansion using the AIM platform technologies
- Announced a preclinical research collaboration with Columbia University Irving Medical Center's Herbert Irving Comprehensive Cancer Center focused on NexImmune's AIM ACT in Columbia's patient-derived organoid models of HPV-associated cancers

Business Updates

- Announced the appointment of Kristi Jones as Chief Executive Officer and Member of the Board of Directors
- Announced the promotion of Mathias Oelke, Ph.D. to Chief Scientific Officer
- Announced the appointment of Dr. Leena Gandhi, Director of Dana-Farber's Center for Cancer Therapeutic Innovation, to NexImmune's Board of Directors
- Announced the formation of the Autoimmune and Infectious Diseases Scientific Advisory Board
- Continued to strengthen the management team with key appointments across the organization

Select 1Q 2022 Financial Highlights

Cash, cash equivalents and marketable securities for the Company as of March 31, 2022 were $65.0 million compared to $81.8 million for quarter ending December 31, 2021. Based upon current operating plans, NexImmune expects that its existing cash, cash equivalents and marketable securities will enable the Company to fund its operating and capital expenditure requirements into the second quarter of 2023.

Research and development expenses were $10.4 million in the first quarter of 2022, compared to $6.0 million for the same period in the prior year. The increase in R&D expenses was mainly attributable to costs for the two clinical trials, as well as personnel-related expenses driven by increased headcount.

General and administrative expenses were $4.6 million, compared to $4.1 million for the same period the prior year. The increase was due primarily to personnel-related expenses and fees related to professional and consulting services.

Net loss, according to generally accepted accounting principles in the U.S. (GAAP), was $15.0 million for the quarter, or a basic and diluted GAAP loss per share of $0.66. This compared to a net loss of $8.5 million, or a basic and diluted GAAP loss per share of $0.71, for the same period the prior year.

About NexImmune

NexImmune is a clinical-stage biotechnology company developing a novel approach to immunotherapy designed to employ the body's own T cells to generate a specific, potent, and durable immune response. The backbone of NexImmune's approach is a proprietary Artificial Immune Modulation (AIM™) nanoparticle technology platform. The AIM technology enables NexImmune to construct nanoparticles that function as synthetic dendritic cells capable of directing a specific T cell-mediated immune response. AIM constructed nanoparticles employ natural biology to engage, activate and expand endogenous T cells in ways that combine anti-tumor attributes of antigen-specific precision, potency and long-term persistence with reduced potential for off-target toxicities.

NexImmune's two lead programs, NEXI-001 and NEXI-002, are in Phase 1/2 clinical trials for the treatment of relapsed AML after allogeneic stem cell transplantation and multiple myeloma refractory to 3 or more prior lines of therapy, respectively. NexImmune is also developing new AIM nanoparticle constructs and modalities for potential clinical evaluation in oncology and in disease areas outside of oncology, including autoimmune disorders and infectious disease.

For more information, visit www.neximmune.com.

Forward Looking Statements

This press release may contain "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the beliefs and assumptions and on information currently available to management of NexImmune, Inc. (the "Company"). All statements other than statements of historical fact contained in this press release are forward-looking statements, including statements concerning our results of operations for the three months ended March 31, 2022; the sufficiency of the Company's current cash, cash equivalents and marketable securities to fund its planned operations into the second quarter of 2023; our planned and ongoing clinical trials for the Company's product candidates, including NEXI-001, NEXI-002 and NEXI-003; the initiation, enrollment, timing, progress, release of data from and results of those planned and ongoing clinical trials and preclinical studies; and the utility of prior preclinical and clinical data in determining future clinical results. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, our ability to continue as a going concern absent access to sources of liquidity and the risks and uncertainties set forth in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission ("SEC") on March 9, 2021, our Quarterly Report on Form 10-Q for the three months ended March 31, 2022 filed with the SEC on May 12, 2022, and subsequent reports that we file with the SEC. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this press release. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this press release to conform any of the forward-looking statements to actual results or to changes in its expectations.

Contacts

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NEXIMMUNE, INC.

BALANCE SHEETS

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,503,334	$ 30,326,352
Marketable securities	40,506,415	51,491,942
Restricted cash	67,500	67,500
Prepaid expenses and other current assets	6,822,410	4,394,916
Total current assets	71,899,659	86,280,710
Property and equipment, net	4,475,089	4,427,307
Operating lease right-of-use assets	1,345,681	—
Other non-current assets	593,525	324,099
Total assets	$ 78,313,954	$ 91,032,116
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,007,994	$ 1,045,159
Accrued expenses	4,497,425	6,170,709
Operating lease liabilities, current	585,916	—
Total current liabilities	7,091,335	7,215,868
Operating lease liabilities, net of current portion	829,440	—
Deferred rent, net of current portion	—	55,581
Total liabilities	7,920,775	7,271,449
Commitments and contingencies		
Stockholders' equity		
Common Stock, $0.0001 par value, 250,000,000 shares authorized, 22,841,794 issued and outstanding as of March 31, 2022 and 22,828,904 shares issued and outstanding as of December 31, 2021	2,284	2,283
Additional paid-in-capital	213,177,933	211,498,827
Accumulated other comprehensive income	(20,578)	3,012
Accumulated deficit	(142,766,460)	(127,743,455)
Total stockholders' equity	70,393,179	83,760,667
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 78,313,954	$ 91,032,116

NEXIMMUNE, INC.

STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended March 31,	
	2022	2021
Revenue	$ —	$ —
Operating expenses:		
Research and development	10,448,843	6,012,608
General and administrative	4,604,679	4,057,592
Total operating expenses	15,053,522	10,070,200
Loss from operations	(15,053,522)	(10,070,200)
Other (expense) income:		
Interest income	33,093	3,613
Change in fair value of derivative liability	—	2,424,877
Gain on extinguishment of debt		—
Interest expense	—	(904,119)
Other expense	(2,576)	(722)

Other income (expense)	30,517	1,523,649
Net Loss	$ (15,023,005)	$ (8,546,551)
Accumulated dividends on Redeemable Convertible Preferred Stock	—	(377,562)
Net loss attributable to common stockholders	$ (15,023,005)	$ (8,924,113)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.66)	$ (0.71)
Basic and diluted weighted-average number of common shares outstanding	22,836,781	12,633,123

STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Net loss	$ (15,023,005)	$ (8,546,551)
Other comprehensive loss:		
Unrealized loss on available-for-sale marketable securities, net of tax	(23,590)	—
Comprehensive loss	$ (15,046,595)	$ (8,546,551)